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IN THE

Supreme Court of the United States

October Term, 1981

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Petitioners,

v.

IVES LABORATORIES, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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REPLY BRIEF OF PETITIONERS DARBY DRUG CO., INC., MD PHARMACEUTICAL COMPANY, INC., RUGBY LABORATORIES, INC., AND SHERRY PHARMACEUTICAL CO., INC.

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POINT I

Color Cannot Be Monopolized: Federal Courts Cannot Grant One Company the Exclusive Right to Use a Color on a Product Others Are Free to Sell.

At the heart of this case is a basic question: should any company have the exclusive right to use a particular color on a product which others are free to sell, thereby preventing competitors from selling the product in the color used by the originator?

Colors have never been granted trademark status by the patent office unless they are part of a fanciful design or symbol. (p. 14 of Darby's Main Brief) Neither have colors alone been granted trademark status by the courts via secondary meaning. (p. 15 of Darby's Main Brief)

It is particularly inappropriate to find that color has acquired trademark status through secondary meaning in this case where consumers do not choose their medication and color can play no role in the selection process, as might be the case if we were dealing with a product selected from a drug store shelf from among other competing products. The consumers of cyclandelate do not see the product until after it is purchased; therefore, color does not influence their choice.

If this court permits color to be used as a trademark in the case at bar, which does not involve consumer choice or selection, the principle thus established would be applicable to products which are chosen by consumers in department stores, supermarkets, drug stores, etc. Thus, the manufacturers of wooden matchsticks, fishing bobs, basketballs or the like would be entitled to establish color monopolies based upon allegations of "secondary meaning". There is no valid ground for departing from the doctrine already applied to matchsticks, fishing bobs, basketballs and the like that color cannot be monopolized as a trademark. (pp. 14-15 of Darby's Main Brief)

The fact that numerous color combinations may be available for drug capsules is not a valid ground for de-

parting from the principle that color cannot be monopolized as a trademark. A manufacturer desiring to sell his product in a single colored capsule does not have numerous colors to choose from. Moreover, courts should not be forced to decide in a multiplicity of law suits whether one company's shade of a particular color is sufficiently different from that of another company so as to avoid infringement.

Even if Ives did establish an association in the minds of consumers between the color of the product and a single source of origin (secondary meaning) by taking advantage of its patent monopoly for the many years during which Ives' blue 200 mg. capsule was the only one available, the courts should not grant Ives trademark rights in color. If Ives truly wanted to establish, in the minds of consumers, a relationship between the appearance of its capsule and the source of the product, Ives should not have relied on color alone to establish that association. Ives should have done what every other trademark aspirant has been required to do, i.e., create a fanciful symbol or design. Such a mark could be imprinted on all Ives' products, not Cyclospasmol alone, thereby truly informing the consumer that Ives is the source of products bearing such symbol or design. If imprinting numbers and letters on capsules is ineffective for "over fifty year old eyes", then Ives should devise some other printed symbol, e.g., a sunburst or a rainbow, that will be effective. Irrespective of the difficulty Ives may encounter in such a project, it should not be permitted to avoid altogether its duty to do so by using color alone as its trademark.

Such a remedy is still available to Ives. It is no answer that imprinting may be inconvenient or expensive. It is Ives that wishes to establish trademark protection for the appearance of its product, and therefore it is Ives' obligation to create a fanciful appearance and not rely solely on color to establish source identification.

Ives claims that a color monopoly is necessary to "alert" the consumer that there has been a change from the medication previously taken in order to counteract unscrupulous druggists. However, the evidence showed that unscrupulous druggists were not a widespread phenomenon. Ives resorts to defamation by innuendo, relying on a study done by the FTC regarding the 1950's which is not in the record, does not relate to present conditions and is of dubious relevancy due to the changes in state drug laws which have been made in the intervening decades. Moreover, Ives has various remedies it can use against the few druggists who engage in trademark infringement, none of which would inhibit competition from generic drug companies. Additionally, Ives benefits from the sanctions imposed by the various states against druggists who engage in passing-off (see Amicus Brief of the N.Y.S. Attorney General).

If colors cannot attain trademark status, courts should not be permitted to grant exclusive use of a color to a particular company by way of remedy, such as was done in the Second Circuit in the case at bar. The monopolization of color by a single company for a particular product should be prohibited, regardless of the rationale used to justify such monopolization.

The reasons for a color monopoly are particularly dubious in this case. The question is not, as Ives would have it, why must generics be made in the same color? Although we answered that question to the satisfaction of the trier of fact, the real question is—why should Ives get a color monopoly? The answer is, it should not.

We ask that this Court reaffirm the principle that color cannot be monopolized, and that federal courts cannot grant one company the exclusive use of a color in connection with a product which others are free to sell.

POINT II

Contributory Trademark Infringement Requires Culpable Conduct to Establish Liability, Not Just "Foreseeability" or "Reasonable Anticipation".

a. Contributory Infringement Requires More Than Foreseeability.

Judge Friendly, in *Ives II*, established the test for determining whether defendants committed contributory trademark infringement; i.e., if they suggested passing-off or mislabeling, or if they continued to sell to a druggist with knowledge or reason to know that the druggist was passing-off or mislabeling.

Ives never proved that a single defendant suggested, even by implication, that a retailer fill a bottle with generic capsules and apply Ives' mark to the label. Nor did Ives prove that a single defendant continued to sell capsules containing the generic drug which facilitated this type of

passing-off to a druggist whom he knew or had reason to know was engaging in such practices.

Judge Mansfield, writing for a majority of the Second Circuit Court of Appeals in *Ives IV*, avoided the dilemma presented by Ives' failure of proof regarding contributory trademark infringement. In *Ives IV*, the majority stated that the defendants could "reasonably anticipate" that their generic product would be passed-off or mislabeled, and that:

> "This amounted to a suggestion, at least by implication, that the druggists take advantage of the opportunity to engage in such misconduct." (*Ives IV* 83a)

Ives apparently recognizes the difficulty of defending the illogic of the Second Circuit, and does not base its argument on any "suggestion" made by defendants to the retail druggists who purchase their cyclandelate. Nor does Ives claim that defendants continued to sell to a druggist with knowledge or reason to know that the druggist was passing-off or mislabeling. At least in this respect, Ives is intellectually more rigorous than the Second Circuit, recognizing that the record contains no evidence of defendant's "suggestions" of "knowledge" of passing-off or mislabeling, either actual or constructive.

In place of the criteria set forth by Judge Friendly in *Ives II*, upon which the case was tried and decided against Ives in the District Court, Ives utilizes a venerable legal doctrine in a novel setting, "reasonable foreseeability" (page 26 of Ives' brief). Never has such a theory been taken from its rightful place in the law of negligence and used to invoke contributory trademark infringement.

As noted by the United States in in its amicus brief, an essential element of contributory trademark infringement should be a showing of active inducement or knowledge of wrongdoing, requiring a guilty state of mind (brief of amicus United States, pages 13-14). Ives would take the "reasonably anticipate" doctrine a step in the other direction—requiring only "foreseeability" of wrongdoing by a retailer to prevent the wholesaler or manufacturer from competing through imitation.

b. Ives Failed to Show That Infringement Was Foreseeable.

Even if "foreseeability" or "anticipation" were proper standards to apply to a contributory infringement claim, there is no basis for Ives' assertion that defendants could "foresee" or "reasonably anticipate" pharmacists' illegal activity because the vast majority of pharmacists are not cheats.* The sole purpose of Ives' pharmacy surveys was to show that a substantial number of pharmacists engage in illegal activity, and Ives failed to do so. The loaded shopping investigation conducted by Ives detail men in cities across the country, at pharmacies which they knew were "bad actors", revealed only 15 instances of illegal substitution. The pharmacy survey conducted by a survey company commissioned by Ives revealed only one

* Since the defendants' blue and blue/red cyclandelate capsules are properly and legally dispensed in the vast majority of cases, the capsules have an obvious non-infringing use. This distinguishes the case at bar from other contributory infringement situations, such as the sale of home video recording equipment, where one might argue that any use of the product causes infringement. Another distinguishing feature is the ability of Ives to locate and to sue the few law-breaking pharmacists who palm-off, there being no need to enter millions of homes for evidence of infringement as might be necessary in the home recording cases.

out of 83 pharmacies that dispensed generically and charged the higher brand name price.

Ives failed to prove that pharmacists are cheats—so even if "foreseeability" or "reasonable anticipation" of wrongdoing by pharmacists were a proper standard for finding contributory trademark infringement, they were not proved at trial. Recognizing its failure of proof, Ives relies on the FTC Report regarding the 1950's which is not in the record, was written at a time when the laws were different from those that exist today and which contradicts the testimony of respondent's own expert witness, the President of the New York State Pharmaceutical Society, that such misconduct by pharmacists is not widespread.

c. There Is No Causal Link Between Capsule Color and Mislabeling.

While relying on the inapposite doctrine of "foreseeability", Ives ignores totally that other venerable requirement of tort liability, causation. No one denies that imitation makes illegal substitution more difficult to detect —but that is not the same as showing that imitation causes illegal substitution. It is perhaps necessary to state the obvious lest it be overlooked: look-alike capsules do not cause illegal drug-substitution. Ives discovered the few instances of illegal substitution by shopping pharmacists with a propensity to pass-off one drug for another. Obviously, it is the propensity of a few pharmacists to engage in such conduct, not look-alike capsules, which causes illegal substitution.

Because the few instances of illegal substitution found by Ives were not sufficient to support its claim of contributory trademark infringement, Ives relied on its *mislabeling* survey to support its §32 claim.

However, capsule color has nothing whatsoever to do with mislabeling. While the defendants admitted the obvious, that imitation facilitates passing-off, no one conceded that color imitation facilitates or is related to mislabeling, and there is a total absence of proof that color imitation causes, facilitates or is related to mislabeling in any way. On reflection, it is apparent why this is so. Passing-off (or illegal substitution) is a practice engaged in surreptitiously by pharmacists, who therefore want to avoid detection while they convert to themselves the excess profit Ives would otherwise make if the brand name product were dispensed. Color imitation facilitates avoiding detection. But mislabeling does not result in excess profit. When a pharmacist "mislabels" he is filling a prescription that permits substitution, and Ives' mislabeling survey showed that only one out of 83 pharmacists charged the brand name price for generic capsules. There is nothing clandestine or surreptitious about mislabeling, as opposed to illegal substitution, and the pharmacist has no need to avoid detection. Therefore, he has no need of look-alike capsules to mislabel.

Since mislabeling is not done for profit, what motivates a pharmacist to mislabel? We suggest there can be only two possible reasons—either (1) he is unfamiliar with the law or the generic name and simply copies the word "Cyclospasmol" from the doctor's prescription pad to the vial label, or (2) he wants the patient to be assured that

there has not been a change in medication. In neither case would the color of the capsule play any role in the mislabeling. In fact, one can postulate that if the generic product legally dispensed were not imitative in appearance, the pharmacist would be more motivated to put "Cyclospasmol" on the label to assure the patient that his maintenance medication was not being changed.*

It is anomalous to prohibit color imitation on the ground that mislabeling exists, even if the practice were widespread, because capsule color imitation does not cause or facilitate mislabeling.

Moreover, even if the practices of mislabeling and passing-off were widespread, Ives is not entitled to an injunction against copying absent a showing that capsule color is an identification of the source of the product. *Wm. R. Warner & Co.* v. *Eli Lilly & Co.*, 265 U.S. 526 (1924). It was Ives' burden to make such a showing. The trial court held that Ives failed to do so and that holding is not clearly erroneous.

We ask the Court to reaffirm that contributory trademark infringement requires some showing of culpable conduct to establish liability—not just "foreseeability" or "reasonable anticipation". We also ask the Court to reverse the illogical and unfounded use of that doctrine by

* It is interesting that the act which Ives calls "mislabeling", i.e., using the brand name when *legally* dispensing the generic drug, is expressly authorized to doctors by N.Y.S. statute, which permits them to use the brand name on their prescription pads (and signing "substitution permitted") when directing that the generic product be dispensed. The legislature thus recognized that, in the prescription drug context, brand names are used generically by doctors.

the Second Circuit to fashion a remedy prohibiting defendants from competing with Ives by imitating the appearance of Ives' product.

POINT III

Ives Failed to Prove Secondary Meaning and, in Any Event, Evidence of Functionality Bars Ives' § 43(a) Claim Based Upon Secondary Meaning.

a. Ives Failed to Show That Capsule Colors Are an Indication of Source.

Ives skillfully avoids a central factual issue in the case, i.e., whether color signifies source of origin to consumers, by simply assuming that color must serve that function absent proof to the contrary. Ives presumes that the appearance of Cyclospasmol was copied with an intent to deceive consumers and that evidence which establishes that colors serve numerous functional purposes is an insufficient excuse for allegedly wrongful copying. Ives also contends that it need only establish that it was the first to adopt the product appearance; that the product was commercially successful; and that the product appearance was subsequently copied. There is no logical or legally cognizable relationship between those facts and the ultimate factual issue of what color actually signifies to consumers. If this were not the case, there would only be a single source of brown cola drinks. *Coca-Cola* v. *The Koke Company*, 254 U.S. 143 (1920).

There is, in fact, only one legitimate method for determining the state of mind of consumers with respect to color and that is to ask them. The patient surveys con-

ducted by Ives for that purpose were a dismal failure and led the trial court to conclude that they "did not constitute proof that the colors had acquired a secondary meaning."

In an attempt to justfy its approach to the secondary meaning issue, Ives relies heavily on the recent wave of decisions, primarily by the courts in the Third Circuit, barring generic drug manufacturers from selling identically colored pharmaceutical capsules and urges that the courts in those cases accepted, as proof of secondary meaning, the same kind of evidence presented here, while simultaneously rejecting the contentions of the generic manufacturers with respect to the functionality of color. It is precisely for that reason that the decisions in those recent cases are wrong and represent a departure from the long line of earlier cases refusing to grant an injunction against the copying of the color of a product. By holding that the mere act of copying creates a presumption of secondary meaning, those cases shift the burden to the defendants and require them to prove a negative—the absence of secondary meaning—rather than properly leaving the affirmative burden of proving secondary meaning with the party asserting the claim. It becomes apparent from a comparison of the earlier cases, which almost uniformly rejected claims that capsule colors could acquire secondary meaning, to the recent Third Circuit cases that the party who has the burden of proof cannot sustain it and therefore loses. Clearly, any attempt to shift that burden of proof to the copyist, based on the mere fact of copying, conflicts with the basic doctrine set forth in *Sears, Compco* and numerous other Supreme Court decisions holding that products in the public domain may be freely copied by anyone.

Ives has never directed any advertising or promotion to consumers which would have educated those consumers to the fact that all products sold under the name "Cyclospasmol", or having the appearance of "Cyclospasmol", emanated from a single source. Accordingly, the claim that secondary meaning exists is based on nothing more than the dubious assumption that patients have somehow acquired a belief that the appearance of a drug capsule is always exclusively associated with a single source. Given the fact that patients have played little or no role in drug selection, there is simply no basis for the assumption. In reality, respondent Ives and similarly situated brand name manufacturers are merely attempting to convert the actual exclusivity which they have enjoyed with respect to a particular product, as a result of patent rights or a lack of competition, into a legal conclusion of secondary meaning. The existence of *de facto* exclusivity does not prove anything with respect to secondary meaning. To the contrary, as the Court found in *Kellogg* and the line of case which follows it, such *de facto* exclusivity may well bar claims to exclusivity based on secondary meaning once the monopoly expires.

b. Defendants' Proof of Functionality Precludes a Finding of Secondary Meaning.

A further fundamental flaw in Ives' approach to the secondary meaning issue is the attempt to convey the impression that any failure by defendants to establish that the capsule colors are functional automatically establishes that the colors have secondary meaning. This is clearly not the law. The brief for the United States correctly points out, based on a long line of decided cases, including

Judge Friendly's decision in *Ives II*, that Ives must overcome two hurdles before it can obtain an injunction which bars the copying of color. First, Ives must establish that consumers associate the capsule color with a single, albeit anonymous, source. Second, even if Ives had established that secondary meaning existed, it would not be entitled to an injunction barring copying of color if the color had functional value, i.e., value apart from identifying the product with a particular source. As the Solicitor General correctly concluded:

> "Thus, a defendant could be held liable only if it copied the 'non-functional' features of another person's product and if, in addition, those features had acquired 'secondary meaning'." Brief, p. 25)

The apparent difficulty which exists in understanding and applying the foregoing fundamental legal concepts is demonstrated by the Solicitor General's own discussion of the secondary meaning and functionality issues despite his correct statement of the basic legal principles. The Solicitor General suggests that claims that capsule colors have therapeutic value or serve substantial other functions are insufficent to permit copying of capsule colors which have acquired secondary meaning. This hypothetical conclusion with respect to a state of facts (the existence of secondary meaning) which does not exist in this case, is based on the unfounded assumption that capsule colors which have significant functional purposes can acquire secondary meaning. The evidence of patient anxiety and confusion resulting from color change and the use of color to identify medications is probative evidence that, at least to that group of patients, the capsule colors signify the medication itself rather that a particular source of origin.

Accordingly, it is the claim that colors which unquestionably have functional attributes have also acquired secondary meaning which requires careful scrutiny and not vice versa as suggested by the Solicitor General. In the face of clear evidence that patients rely on product appearance for a variety of purposes unrelated to the identity of any source of manufacture, there can be no claim based upon secondary meaning.

POINT IV

Imitation of Capsule Appearance by Generic Drug Equivalents Does Not Deceive Consumers as to Source.

In place of logical arguments based on the evidence to show that Ives met the burden of proving defendants' suggested illegal activity or continued to sell to a druggist with knowledge, or reason to know, of his illegal practices, Ives and its amicus supporters rely on "red herrings" and scare tactics. The first such argument is that consumers are deceived by defendants' use of look-alike capsules.

Consumer deception as to source can only result from the misuse of a trade name or symbol which is associated with source. If capsule color is not shown to be a indication of source in the mind of the consumer, the use of capsule color cannot be deceptive as to the source of the capsule or its content.

There was no showing of an association between capsule color and source. A preponderance of the evidence was to the contrary, i.e., that patients or consumers asso-

ciate capsule appearance with the drug itself and its therapeutic effect. Typically a consumer thinks of his "red heart pill" or his "white blood pressure pill"—and not "his blue pill that comes from Ives." Judge Nickerson so found,* and his finding conforms to our shared experience that capsule or tablet appearance does not indicate that the product comes from a single source, as does a symbol or trademark. Look-alike capsules do not deceive the consumer about the source of the product. The look-alike capsule, rather than deceiving the consumer about anything, assures him that he is getting the same drug product he has previously received, but at a cheaper price.

The factitious concern of Ives and its amicus supporters for the rights of consumers, misleads the Court about the real issues presented by this case. Ives and the brand

* We should not be deceived by the sophistic argument that the finding of functionality by the trial court was a legal conclusion and not a finding of fact. The court heard conflicting testimony from expert witnesses on this subject—some saying that a change in color creates the impression that something is wrong with the medication dispensed, and others denying that reaction or minimizing its significance. The trier of fact heard the testimony and concluded that it preponderated in favor of petitioner's claim of functionality. That was his *job* and his finding should be respected unless it is clearly erroneous. Not even the majority of the Court of Appeals, straining to justify its reversal of the District Court, could declare the finding of functionality, based as it was on substantial testimony of professionals, clearly erroneous. The fact that the evidence of functionality was unpersuasive to the majority of the Court of Appeals, is irrelevant. The finding of functionality should stand. Moreover, it makes sense and conforms to our commonly shared experience that (a) capsule color is associated with the medicine and its effects, not with source; (b) a change in capsule color gives the impression that the prescription was filled incorrectly (an improper impression in the case of generic equivalents) and (c) capsule color is important for the large proportion of multi-medicating patients who put their pills in a single container for daily consumption and rely on color to communicate with their doctors and to follow their doctors' prescription instructions.

name drug companies are interested in profits—as are the defendants. Ives seeks to limit competition by placing the defendants at a disadvantage, depriving them of the right to sell a product in the appearance in which consumers are used to seeing it. The association of the product and its appearance was built up during the extended period of Ives' patent monopoly—not as a result of Ives' promotion of the product to consumers, which was insignificant because the product is a prescription drug. The real issue is not consumer deception or consumers' rights, as Ives disingenuously contends, but the competitive advantages associated with a patent monopoly, which Ives seek to extend into the post-patent period. Ives seeks, and was granted by the Second Circuit majority, the exclusive use of the colors associated in the minds of consumers with the product, to that defendants must sell the product in a way that will arouse suspicions that it is a different product, and will create confusion in following prescription instructions.

To the extent that pharmacists infringe upon Ives' trademark, Cyclospasmol, Ives and its brand name brethren have shown the ability through shopping surveys and investigations to root out the few who engage in such activity. Rather than attack the wrongdoers, Ives and its cohorts attack their generic drug competitors. A change in the color of prescription drug capsules, taken as maintenance medication over a long period, gives the consumer the impression that "there is something wrong with the way this prescription has been filled." Ives knows that anxious questions and late night emergency phone calls to doctors and pharmacists will be inevitable. Doctors

will also be reluctant to prescribe generically if the pills sold in unfamiliar colors make patient-doctor communication, and following prescription instructions, more difficult. Ives' hope is that these problems will lead to a higher proportion of doctors signing the "dispense as written" line on the prescription form, and to pharmacists refusing to stock generic products which are different in appearance from the brand name innovator's product. The motive is transparent; Ives seeks to impede competition, not mislabeling or illegal substitution.

POINT V

The Grant of Certiorari Was Appropriate.

Ives supporter, the Pharmaceutical Manufacturers Association (PMA), in its amicus brief, suggests that this Court improvidently granted certiorari inasmuch as the Second Circuit did not determine Ives' §43a claim. PMA's position ignores important facts.

The Second Circuit, in *Ives IV*, established a novel and dangerously expansive standard of liability for contributory trademark infringement under §32. This new doctrine can seriously inhibit competition and is an important issue worthy of this Court's attention.

Moreover, defendants are now enjoined from manufacturing or marketing their "look-alike" capsules and Ives has been granted a monopoly of color in apparent contravention of the principles prohibiting the granting of color monopolies and the principles favoring free competition as enunciated by this Court in *Sears* and *Compco*.

This Court has unquestionable jurisdiction to determine respondent's §43a claim. (*E.g., New York City Transit Authority* v. *Beazer*, 440 U.S. 568, 99 S.Ct. 1355, 1364 n. 24, 59 L.Ed. 2d 587 [1979]; *Ohio Bureau of Employment Services* v. *Modory*, 431 U.S. 471, 97 S.Ct. 1898, 1905, 52 L.Ed. 2d 513 [1977]; *see, generally*, Wright, Miller & Cooper, Vol. 18, Federal Practice & Procedure: Jurisdiction §4036 [1976].) When a case is filed in the Court of Appeals, this Court may grant certiorari, and the scope of review is approached entirely as a matter of wise judicial administration within a single system of courts. (Wright, Miller & Cooper, *supra* at p. 10.)

The law governing Ives' 43a claim was carefully considered by Judge Friendly in *Ives II;* the facts governing Ives' 43a claim were the subject of considered findings by the trial court (*Ives III*); and Ives' 43a claim was discussed in Judge Mulligan's dissent in *Ives IV* and briefed by Ives and other parties and amici. Contrary to PMA's assertion, the 43a claim may be addressed by this Court and the case need not be remanded should the Second Circuit be reversed.

Finally, if this Court determines that color cannot be monopolized under the circumstances presented by this record, Ives' claim under 43a must fail and remand would be unnecessary.

Conclusion

The judgment of the United States Court of Appeals for the Second Circuit (*"Ives IV"*) appealed from herein should be reversed.

Respectfully submitted,

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